

## 510(k) Summary

SEP 24 2010

**Contact:** Mr. Justin Eggleton  
Musculoskeletal Clinical & Regulatory Advisers, LLC  
1331 H Street NW, 12<sup>th</sup> Floor  
Washington, DC 20005  
202.552.5800

**Date Prepared:** July 1, 2010

**Device Trade Name:** STALIF MIDLINE™

**Manufacturer:** Centinel Spine, Inc  
505 Park Ave. 14<sup>th</sup> Floor  
New York, NY 10022

**Classification:** 21 CFR §888.3080, Intervertebral body fusion device

**Class:** II

**Product Code:** MAX

### Indications For Use:

The STALIF MIDLINE™ is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach.

The STALIF MIDLINE™ is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems.

The STALIF MIDLINE™ system must be used with bone grafting material (autograft only).

### Device Description:

The STALIF MIDLINE™ is a radiolucent intervertebral body fusion device and unicortical cancellous bone screws intended to be used without supplemental fixation. The purpose of this 510(k) is to modify the STALIF™ TT (K073109) to include a modified anti-back out feature and additional sizes.

**Predicate Device(s):**

STALIF MIDLINE™ was shown to be substantially equivalent to the previously cleared STALIF™ device (K073109) and has the same indications for use, design, function, and materials used.

**Performance:**

Testing performed in accordance with ASTM F2077 (static/dynamic compression, static/dynamic torsion, static/dynamic compression-shear) and ASTM F2267 (static subsidence) indicates the STALIF MIDLINE™ is mechanically equivalent to predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room --WO66-G609  
Silver Spring, MD 20993-0002

Centinel Spine, Inc.  
% Musculoskeletal Clinical and  
Regulatory Advisers, LLC  
-- Mr. Justin Eggleton  
1331 H Street NW, 12<sup>th</sup> Floor  
Washington, District of Columbia 20005

SEP 24 2010

Re: K101301  
Trade Name: STALIF MIDLINE™  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: September 2, 2010  
Received: September 3, 2010

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K101301

## Indications for Use

SEP 24 2010

510(k) Number (if known): K101301

SEP 24 2010

Device Name: STALIF MIDLINE™

The STALIF MIDLINE™ is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach.

The STALIF MIDLINE™ is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems.

The STALIF MIDLINE™ system must be used with bone grafting material (autograft only).

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K101301